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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,088	07/23/2001	David W. Ow	16313-0052	4013

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EXAMINER

HELMER, GEORGIA L.

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/911,088

Applicant(s)

OW, DAVID W.

Examiner

Georgia L. Helmer

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Prior for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16, 35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 35 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response; dated 11 August 2003.
2. Applicant has amended claims 1, 6, 8, and 9. Claims 1-16, 35 and 36 are pending, and are examined in the instant action.
3. Applicant needs to remove nonelected invention(s) from the claims. Specifically, in claim 35, a "mammalian cell" needs to be deleted.
4. This action is made FINAL necessitated by Applicant's amendment.
5. All rejections not addressed below have been withdrawn.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. It is noted that Applicant has included reference articles with this Response. However, a proper submission of references must comply with 37 CFR 1.97 and include a filled-out PTO 1449 for consideration by the Office.

### ***Claim Rejections - 35 USC § 112-second***

8. Claims 1-16, 35 and 36 are rejected under 35 U.S.C. 112-2<sup>nd</sup>.

In claim 1, and all claims dependent thereon,

In (a), "receptor polynucleotide" is unclear because it is not apparent how a "receptor polynucleotide" differs from a polynucleotide.

Applicant traverses, stating primarily that in ¶ 34 of the specification, in one embodiment of the invention comprises a method for the replacement of a DNA of interest, through the use of an irreversible recombinase to replace a receptor polynucleotide with a donor polynucleotide. As such, a “receptor polynucleotide” refers to the DNA of interest that is replaced by a second DNA of interest.

Applicant's traversal has been considered and is not persuasive because the limitations of the specification, unless stated in the claims, are not read into the claims. Applicant has given an example (¶ 34) but an example is not a definition. Accordingly this rejection is maintained.

Applicant traverses, stating primarily that in ¶ 34 of the specification, in one embodiment of the invention comprises a method for the replacement of a DNA of interest, through the use of an irreversible recombinase to replace a receptor polynucleotide with a donor polynucleotide. As such, a “donor polynucleotide” refers to the DNA of interest that is replaced by a second DNA of interest.

Applicant's traversal has been considered and is not persuasive because the limitations of the specification, unless stated in the claims, are not read into the claims. Applicant has given an example (¶ 34) but an example is not a definition. Accordingly this rejection is maintained.

***Claim Rejections - 35 USC § 112-Enablement***

Art Unit: 1638

9. Claims 1-16, 35 and 36 remain rejected under 35 U.S.C. 112, first paragraph, for reasons of record. The Office maintains that *Arabidopsis thaliana* is not representative of all plants, as discussed previously.

Applicant traverses, stating primarily (Response p.8) that the claimed method has been shown to be effective in organisms as diverse as yeast, human cells and plants. And that Applicant has shown how to make and use the invention in three widely diverse species and it is therefore submitted that the use of the claimed method to replace a nucleic acid sequence is enabled for eukaryotic cells. Applicant further traverses, saying that Applicant has previously shown that the  $\phi$ C31 recombinase system can perform site-specific recombinase in tobacco, with a genome size 20 fold higher than *Arabidopsis thaliana* (citing WO0107572A2, examples 4 and 5) . Additionally, Applicant has shown that success with the gene replacement system described and claimed in the instant application with both mouse and human cells.

Applicant's traversal has been considered and is unpersuasive because Example 4 teaches excision, which involves only a single crossover event of the DNA, and example 5 involves only the single crossover DNA event, in the insertion event. Claims of the instant case are drawn to replacement of one DNA sequence by another DNA sequence—this requires two single crossover events ( or one double crossover event). Applicant has not enabled this more complex event.

Applicant traverses, stating primarily (Response, p. 9) that there is not a single documented case where a site-specific recombinase system worked in a small genome plant but will not work in a large genome plant. Applicant's traversal has been considered and is unpersuasive because negative examples and negative findings rarely get published. Therefore, lack of such documentation is not probative.

Applicant traverses, stating primarily (Response, p.9) that larger genome size might possibly effect the efficiency of site-specific recombination, but not the specificity of the reaction, using as reference the Cre-lox system in tobacco and wheat. Applicant's traversal has been considered and is unpersuasive because the Cre-lox system is a reversible site-specific recombinase system and differs from the  $\phi$ C31 system in a number of ways. Furthermore, genomic size can certainly effect the rate of the reaction, and if the rate is low enough, will effectively preclude the reaction occurring in any reasonable timeframe. Accordingly, this rejection is maintained.

#### Remarks

10. No claim is allowed.

Art Unit: 1638

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

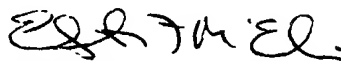
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Art Unit: 1638

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service, whose telephone number is 703-308-0196.

Georgia Helmer PhD  
Patent Examiner  
Art Group 1638  
October 31, 2003

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600